UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LEON D. BOROCHOFF, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. GLAXOSMITHKLINE PLC, et al., Defendants.	Civil Action No. 1:07-cv-05574-LLS CLASS ACTION REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR RECONSIDERATION

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Lead Plaintiff Avon Pension Fund, Administered by Bath & North East Somerset Council and Plaintiffs Plumbers & Steamfitters Local 773 Pension Fund and Plumbers' Union Local No. 12 Pension Fund (collectively, "Plaintiffs") respectfully submit this Reply Memorandum of Law in further support of their motion for reconsideration ("Motion") of this Court's Opinion and Order ("Decision," referenced herein as "Decision at __"), dated May 9, 2008 and entered on May 13, 2008, which granted the motion to dismiss the Amended Class Action Complaint (the "AC") filed by Defendants GlaxoSmithKline plc ("Glaxo" or the "Company"), Jean-Pierre Garnier, Ph.D. ("Garnier"), David Stout ("Stout"), Julian Heslop and Simon Bicknell (collectively, "Defendants").

I. PRELIMINARY STATEMENT

In opposition to Plaintiffs' motion for reconsideration, Defendants assert that Plaintiffs have not cited to any "new" facts which would permit the Court to reconsider its decision and that even if the Court reconsidered its decision and permitted Plaintiffs to amend the AC and file the [Proposed] Second Amended Complaint (the "PSAC"), the new allegations do not cure the deficiencies identified by the Court. As set forth herein, Defendants are wrong on both counts.

As set forth in Plaintiffs' opening memorandum, Plaintiffs have identified substantial new facts that were learned after the filing of the Amended Complaint (the "AC") and these new facts go directly to key issues in this case. For example, a centerpiece of Defendants' scienter argument has been that Glaxo shared the Meta-Analyses (as that term has been defined by the parties and the Court) with the United States Food and Drug Administration (the "FDA") and, therefore, did not act with intent to conceal any testing information. *See, e.g.*, Defendants' Memorandum Of Law In Support Of Defendants' Motion To Dismiss Amended Complaint, dated December 13, 2007 (hereinafter "Def. Mem. at __") at 45 (arguing that Glaxo had no intent to defraud because it shared Meta-Analyses with FDA); Decision at 19 ("GSK disclosed its meta-analyses results to the FDA, and posted them to its website, which rebuts any intent to defraud."). On March 25, 2008, however,

the FDA issued a warning letter to the Company (the "Warning Letter") (attached as Exh. C to Plaintiff's Motion for Reconsideration), which stated, among other things, that Glaxo had "failed to report data relating to clinical experience along with other data and information, for Avandia as required" by applicable regulations. Thus, Glaxo did not share all Avandia-testing related data with the FDA on a timely basis and its failure to do so interfered with the FDA's "ability to spot safety trends." This further supports Plaintiffs allegations that Defendants acted to conceal the link between Avandia and the increased risk of heart attacks from the public and investors. The Warning Letter was made public long after Plaintiffs filed the AC (November 13, 2007) and their opposition to Defendants' motion to dismiss the AC (January 14, 2008) and, therefore, is a "new" fact.

Furthermore, the PSAC now details a litany of negative Avandia-related sales announcements from Glaxo which evidence the deterioration in sales of Avandia due to, in material part, the public announcement that there was a link between use of Avandia and an increased risk of heart attacks. These earnings reports, *see* ¶79[1] (February 7, 2008, Glaxo reports financial results for forth quarter 2007 and fiscal year 2007) and ¶81 (April 23, 2008, Glaxo reports fiscal results for first quarter 2008), each of which were issued after the filing of the AC, are "new" facts and support Plaintiffs' allegations that the conclusions of the Meta-Analyses contained serious adverse information about Avandia which linked it to an increased risk of heart attack and was required to be disclosed.

Moreover, the PSAC now alleges that the Meta-Analyses showed that there was a statistically significant link between use of Avandia and heart attacks. *See* ¶¶5, 43, 44 and 46. Plaintiffs have further supported these allegations by alleging that an FDA advisory committee

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[1] "¶___" refers to the paragraphs of the PSAC.

reviewed the underlying data used in the Meta-Analyses and concluded that "there is an excess risk, statistically significant" with the use of Avandia and heart attacks and that the Meta-Analysis conducted by Dr. Steven Nissen, which reviewed virtually the same set of data as the Meta-Analyses, concluded that there was a statistically significant connection between the use of Avandia and heart attacks. *See* ¶¶69 and 74. These allegations further particularize Plaintiffs' allegations of fraud and the Second Circuit has long held that leave to amend should be given when the dismissal is predicated on a failure to plead fraud with particularity. The most that Defendants can do with these allegations is raise inappropriate factual arguments and label the allegations "conclusory."

The new allegations, coupled with other revisions to the AC as set forth in the PSAC, make clear that Plaintiffs have identified new facts and are able to satisfy the deficiencies cited by the Court in the Decision. Accordingly, it is respectfully submitted that justice will be best served by permitting Plaintiffs to amend the AC and file the PSAC.

II. ARGUMENT

A. Reconsideration of the Decision Is Appropriate and This Court Can Exercise Its Discretion and Reconsider Its Decision Denying Plaintiffs Leave to Amend the AC

Contrary to Defendants' contention, courts are afforded general discretionary power to grant a motion for reconsideration as they see fit. *See Lugo v. Artus*, 05 Civ. 1998 (SAS), 2008 U.S. Dist. LEXIS 22562 (S.D.N.Y. Mar. 20, 2008) ("Motions for reconsideration are committed to the sound discretion of the district court"); *see also McBride v. Unum Provident*, 6:07-CV-0232 (NPM/GJD), 2008 U.S. Dist. LEXIS 50323 (N.D.N.Y. July 1, 2008) ("The decision to grant or deny a motion for reconsideration falls squarely within the discretion of the district court.") (citing *Devlin v.*

Transportation Communications International Union, 175 F.3d 121, 132 (2d Cir. 1999)).[2]

Here, it is respectfully submitted that justice requires that the Court permit Plaintiffs to amend the AC because, as set forth in detail below, Plaintiffs have identified "new" facts which bear directly on key issues in this case. Indeed, the Warning Letter was made publicly available in April 2008, long after the filing of the AC and Plaintiffs' opposition to Defendants' motion to dismiss. As discussed further herein, the Warning Letter further supports Plaintiffs' contentions that Defendants acted recklessly. Defendants weakly argue that the Warning Letter is not "new" because it was publicly available before the Court issued its decision. Def. Opp. at 7. (References to Def. Opp. at __ refer to Defendant's Opposition to Plaintiff's Motion for Reconsideration). The Decision was issued on May 9, 2008, a few weeks after the issuance of the Warning Letter. This is a very brief period of time and Plaintiffs can not be criticized for delay. In any event, given Defendants' repeated statements to the Court that Glaxo shared all testing information with the FDA, Defendants should have brought the Warning Letter to the Court's attention as it was relevant to their statements to the Court.

Similarly, Glaxo's earnings announcements all (with the exception of one release) post-date the filing of the AC. The PSAC provides details of Glaxo's earnings releases which were issued on the following dates: October 24, 2007; February 7, 2008; and April 23, 2008. In these releases, Glaxo admits, among other things, that sales of Avandia have declined dramatically "following

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[2] Defendants cite *In re Health Mgmt. Sys., Inc. Sec. Litig.*, 113 F. Supp. 2d 613, 614 (S.D.N.Y. 2000) for the proposition that the standard for a reconsideration motion is "strict" and rarely granted. Def. Opp. at 4. That case, however, involved reconsideration of an award of attorneys' fees where the attorneys sought to offer additional clarification for their application after the requested fee was reduced. The Court noted that it had already considered all of this information and reviewed the application in great detail. Here, Plaintiffs have not sought to clarify information already submitted to the Court.

publication in May of a meta-analysis." ¶¶76, 79 and 81. The earnings releases support Plaintiffs' allegations that the conclusions of the Meta-Analyses raised serious issues about the use of Avandia and were required to be disclosed. Indeed, the fact that the public clearly viewed the meta-analysis of Dr. Nissen as important is demonstrated by the decline in Avandia sales. *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001) ("Any information that sheds light on whether class period statements were false or materially misleading is relevant."); *In re Vivendi Universal, S.A. Sec. Litig.*, No. 02 Civ. 5571 (RJH), 2004 U.S. Dist. LEXIS 7015, at *22 (S.D.N.Y. April 22, 2004) (noting that the "Second Circuit has explicitly recognized that plaintiffs may reply on post-class period data to confirm what a defendant should have known during the class period.").

As detailed below, these "new" facts go directly to key issues in this case and provide a sufficient basis for the Court to reconsider its decision denying Plaintiffs the opportunity to amend the AC. *See Menkes v. Stolt-Nielsen SA*, Case 3:03-cv-00409-DJS (D. Conn. Jan. 27, 2006) (Electronic Order on "Order on Motion for Reconsideration" – Docket Entry #52) (on reconsideration, the court modified its dismissal with prejudice to a dismissal without prejudice in order to allow plaintiffs to replead their allegations of scienter based on new facts); *Menkes v. Stolt-Nielsen S.A.*, No. 3:03CV409(DJS), 2006 U.S. Dist. LEXIS 42644 (D. Conn. June 19, 2006) (denying defendants motion to dismiss after plaintiff replead the scienter allegations based on newly discovered evidence). *See* Exh. A attached hereto.

Defendants' authorities do not hold otherwise as they involve circumstances distinguishable from this case. In *Donovan v. Sovereign Sec. Ltd.*, 726 F.2d 55, 60 (2d Cir. 1984), for example, the Second Circuit simply held that where a party allowed the time to appeal to lapse it could not later attack the underlying judgment by seeking to relitigate issues decided by the original judgment. And, the holding in *Frankel v. ICD Holdings S.A.*, 939 F. Supp. 1124, 1127 (S.D.N.Y. 1996)

concerned summary judgment and in that context held that a motion for relief under Fed. R. Civ. P. 60(b) could not be used to focus on different evidence that was available at the time of the motion practice.

Even Defendants' authorities support Plaintiffs' contention that the Court should review the PSAC and determine if setting aside its prior judgment is appropriate. *See Nat'l Petrochemical Co. of Iran v. M/T Stolt Sheaf*, 930 F. 2d 240, 244 (2d Cir. 1991) ("Of course in view of the provision in Rule 15(s) that 'leave [to amend] shall be freely given when justice so requires,' *see Foman v. Davis*, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962), it might be appropriate in a proper case to consider the nature of the proposed amendment in deciding whether to vacate the previously entered judgment."); *In re Star Gas Sec. Litig.*, 241 F.R.D. 428 (D. Conn. 2007) (noting that under certain circumstances it would be appropriate for the Court to review a proposed amended pleading when considering whether to vacate judgment but finding that Plaintiffs had been given an opportunity by the Court and declined to do so and that a review of the proposed amended pleading demonstrated that it contained nothing new); *Antigenics, Inc. v. U.S. Bancorp Piper Jaffray, Inc.*, No. 03-0971, 2004 US Dist. LEXIS 20405 (S.D.N.Y. Oct. 8, 2004) (reviewing proposed amended complaint to determine whether judgment should be vacated and finding the proposed amendment was insufficient).

B. The PSAC States a Claim Under the Exchange Act

1. Defendants Were Required to Disclose the Meta-Analyses

The PSAC alleges that the Meta-Analyses showed a statistically significant link between the use of Avandia and adverse cardiovascular events. ¶¶5, 43, 44 and 46. Defendants contend that this revision is nothing more than "conclusory." Def. Opp. at 7. The PSAC, however, supports its allegations of statistical significance by, among other allegations, adding new allegations that: (i) an FDA advisory committee reviewed the Meta-Analyses and found a statistically significant link

between Avandia and increased risk of heart attacks; and (ii) Dr. Nissen's meta-analysis found a statistically significant link between use of Avandia and an increased risk of heart attacks.[3]

These allegations provide an additional basis for Plaintiffs' allegations that the Meta-Analyses showed a statistically significant link between use of Avandia and increased risk of heart attacks.[4] Indeed, the fact that an FDA advisory committee and Dr. Nissen reviewed the same data that was contained in the Meta-Analyses – and found a statistically significant link – further supports Plaintiffs' allegations that the Meta-Analyses showed a statistically significant link between Avandia and the increased risk of heart attack. Defendants, therefore, were required to disclose them.

Recently, similar allegations were found sufficient in *In re Pfizer Inc. Sec. Litig.*, No. 04 Civ. 9866 (LTS)(DCF), 2008 U.S. Dist. LEXIS 50923 (S.D.N.Y. July 1, 2008) ("*Pfizer*"). In *Pfizer*, plaintiff alleged that defendants failed to disclose the results of several clinical trials/studies

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[3] *See also*, Dr. Steven E. Nissen, M.D., Chairman of the Department of Cardiovascular Medicine at Cleveland Clinic and the Immediate Past-President of the American College of Cardiology (ACC), stated in his Oral Testimony to the House Committee on Oversight and Government Reform that the meta-analysis he performed based on Glaxo's own clinical trials on Avandia "showed a 43% excess incidence of heart attack in Avandia-treated patients, which was statistically significant." *See* Exh. B attached hereto. Also, Bruce M. Psaty, M.D., Ph.D., a professor of medicine and epidemiology at the University of Washington, testified before the House Committee on Oversight and Government Reform and stated that "Avandia was associated with a significant 43% increase in the risk of heart attacks" and later added that "there is still statistically significant evidence of harm." *See* Exh. C attached hereto. *The New England Journal of Medicine* ("*NEJM*") article stated: Avandia "was associated with a significant increase in the risk of myocardial infarction."

[4] To the extent that the Decision can be construed to hold that Plaintiffs' failed to particularize their allegations of fraud, it is appropriate for the Court to permit Plaintiffs the opportunity to remedy the pleading deficiencies. *See Chill v. GE*, 101 F.3d 263, 271 (2d Cir. 1996) ("In general, leave to amend should be freely granted, especially where dismissal of the complaint was based on Rule 9(b), and there must be good reason to deny the motion."); *Radha Bhavatarini Devi Narumanchi v. Federal Emergency Mgmt. Agency*, No. 99-6139, 1999 U.S. App. LEXIS 30444 (2d Cir. Nov. 18, 1999) ("In general, leave to amend "'should be freely granted, especially where dismissal . . . was based on Rule 9(b).'")

concerning two of Pfizer's drugs, Celebrex and Bextra which evidenced an increased risk of negative cardiovascular effects. *Pfizer*, 2008 U.S. Dist. LEXIS 50923, at *7, *11. As here, defendants argued that the studies did not demonstrate statistically significant evidence of adverse cardiovascular events and that the clinical trials/studies suffered from various defects. *Id*. at *18-*20. The Court rejected those arguments holding that the issue of statistical significance was an inherently factual issue that it could not decide on a motion to dismiss and that the purported infirmities in the clinical trials was also a factual issue not appropriate for resolution on a motion to dismiss. The Court reasoned that "[a]lthough there are aspects of the studies that could lead a fact finder to discount the significance of their results, such as the relatively small sample sizes and the small percentage increases in cardiovascular events, the Court cannot say at this point that, when the facts are viewed in the light most favorable to Plaintiffs, the studies are statistically insignificant as a matter of law." *Id*. at *28.[5]

Furthermore, as evidenced by the declining Avandia sales, the conclusions of the Meta-Analyses was serious adverse information which demonstrates a significant problem with Avandia and were therefore required to be disclosed. Decision at 15 (noting that Defendants were only required to disclose the Meta-Analyses if they showed that the heart attack risk was "sufficiently serious").

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[5] The Court in *Pfizer* also distinguished the holding in *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F. 3d 153, 157 (2d Cir. 1998) as involving a situation where the company had six (6) adverse event reports about the use of a drug. This limited amount of information clearly did not link the drug to "adverse health consequences." *Pfizer*, 2008 U.S. Dist. LEXIS 50923, at *21. By contrast, in Pfizer, as in this case, defendants had possession of studies showing a link between use of a drug and adverse health consequences.

2. Defendants Acted with Recklessness

As the PSAC adequately alleges that Defendants were under a duty to disclose the Meta-Analyses, it adequately alleges that Defendants acted with recklessness and conscious misbehavior. *See Pfizer*, 2008 U.S. Dist. LEXIS 50923, at *40 ("Because Plaintiffs have alleged adequately that Defendants were aware of studies containing statistically significant links between Celebrex/Bextra and illness, Plaintiffs have satisfied their burden of alleging facts giving rise to a strong inference of fraudulent intent.").

Furthermore, the PSAC adds additional allegations concerning Defendants' intimidation of Dr. Buse and Defendants' failure to submit Avandia clinical trial data to the FDA in a timely manner. With respect to Dr. Buse, the PSAC provides extensive detail on Defendants' actions[6] and how Defendants recognized that any connection between use of Avandia and heart attacks would be detrimental to sales of the drug. *See* ¶¶3, 4, 7, 35-42. These allegations further underscore Defendants' intent to conceal adverse Avandia information from the market.

With respect to Defendants' failure to provide Avandia study-related information to the FDA, the PSAC alleges that Glaxo failed to submit important test data to the FDA. Defendants have argued, and this Court accepted, that Defendants' disclosure of the Company's Meta-Analyses results to the FDA rebuts any allegation that Defendants sought to conceal information.[7] This exact

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[6] This Court's Decision reasoned that Dr. Buse's views were not excluded from the "total mix" of information available to the public. *See* Decision at 23. Plaintiffs respectfully disagree. The Committee Staff Report, which was not released until November 2007, clearly details how most (if not all) of the evidence of the intimidation of Dr. Buse by Defendants was gleaned from internal and other non-public documentation. Clearly, the allegations pertaining to Dr. Buse – and the manner in which Defendants knew of the risks associated with Avandia, yet chose to suppress from the public – is newly discovered.

[7] In support of their motion to dismiss and opposition to Plaintiffs' instant Motion, Defendants repeatedly asserted to this Court that the Company disclosed the data and results of its studies

position was rejected in the *Pfizer* case. The Court stated:

> Defendants also contend that, because they disclosed the studies to the FDA, they did not conceal them in violation of any obligations imposed by the securities laws. This argument is also inappropriately fact-based [*31] and incorrectly presumes that disclosure to the FDA is equivalent to disclosure to the market. Although it is likely the FDA would highlight or require disclosure of material negative safety information about a drug, the FDA is not the arbiter of materiality for purposes of the securities laws. Rather, an alleged omission is material if there is a substantial likelihood that the disclosure of the omitted fact would be viewed by the reasonable investor as having significantly altered the "total mix" of information made available. *Halperin v. eBanker USA.Com, Inc.*, 295 F.3d 352, 357 (2d Cir. 2002). "The 'total mix' of information includes 'information already in the public domain and facts known or reasonably available to the shareholders.'" *In re Regeneron Pharmaceuticals, Inc. Sec. Litig.*, No. 03 Civ. 3111, 2005 U.S. Dist. LEXIS 1350, 2005 WL 225288, at *14 (S.D.N.Y. Feb. 1, 2005) (*quoting Rodman v. Grant Found.*, 608 F.2d 64, 70 (2d Cir. 1979)). Disclosure to the FDA does not by itself provide a safe harbor under the securities laws.
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> *Pfizer*, 2008 U.S. Dist. LEXIS 50923, at *31.

More importantly, the revelation of a recent investigation conducted by the FDA uncovered that Glaxo has not timely shared all Avandia-related testing data to the FDA.[8] In an article dated

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pertaining to the Company's Avandia drug. *See, e.g.*, "GSK shared its meta-analysis results with the FDA as they became available." (Def. Mem. at 4); "GSK submitted summary information to the FDA 'showing preliminary results' of the Company's meta-analysis of data derived from the 37 Avandia clinical trials . . ." (Def. Mem. at 17); "GSK . . . submitted the final report of this analysis to the FDA in August 2006." (Def. Mem. at 17); "GSK provided the final results of this Balanced Cohort Study to the FDA at the same time it submitted the completed meta-analysis." (Def. Mem. at 19); "GSK submitted its final reports for the meta-analysis and Balanced Cohort Study to the FDA in August 2006." (Def. Mem. at 20); "GSK disclosed its meta-analysis results to the FDA . . ." (Def. Mem. at 45); "GSK voluntarily disclosed to the Food and Drug Administration ('FDA' or 'Agency') the results of its Avandia 'meta-analysis' . . ." Reply Memorandum in Support of Defendants' Motion to Dismiss Amended Complaint, filed February 13, 2008, at 1. (Referenced herein as "Def. Reply at __"); *see also* Def. Reply at 10. Defendants continually represented to this Court that they did not hide anything from the FDA regarding studies conducted by Defendants in connection with Avandia. Defendants failed to mention that they had failed to report extensive Avandia-related testing data to the FDA for an extensive period of time.

[8] Defendants argue that this information was publicly available after Defendants' motion to dismiss was fully briefed, yet before this Court issued its Decision. Def. Opp. at 7. Defendants rely on two decisions – *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 59 (1st Cir. 2008) and *Pugh v.*

April 8, 2008, *Reuters* reported that Glaxo "failed to report all of the required post-approval data on its diabetes drug Avandia." *Reuters*, "FDA says Glaxo failed to report Avandia data," Apr. 8, 2008 (attached hereto as Exh. D). That same day, *Bloomberg* likewise reported that approximately 20 studies were either never relayed to the FDA by Glaxo or were not included in the Company's required annual reports to the FDA between 2001 and 2007. *Bloomberg*, "Glaxo Failed to Disclose Avandia Studies, FDA Says," Apr. 8, 2008 (attached hereto as Exh. E). Dr. Stephen Nissen suggested that Glaxo's withholding of information precluded the FDA from adequately assessing the safety of drugs and to adequately warn the users of Avandia of the dangerous side-effects linked to the drug. The *Bloomberg* article quoted Dr. Nissen as saying "[t]he FDA can only do its job if they have all of the information that is required by law." Both articles (as well as a multitude of others published on April 8, 2008) referenced the Warning Letter. In the "Warning Letter," the FDA admonished Glaxo for the Company's non-compliance, deviations and failure to report adverse data and findings pertaining to Avandia.

It is respectfully submitted that these allegations, coupled with the other allegations in the PSAC, sufficiently raise a strong inference that Defendants acted with a conscious disregard for the truth of their statements.

Tribune Co., 521 F.3d 686, 698 (7th Cir. 2008) – to support their misguided position that Plaintiffs' less than ***one month*** delay in bringing this information to the Court's attention is fatal to Plaintiffs' right to amend the AC. Neither case, however, has any bearing to this case. In *ACA*, the plaintiff waited years after the newly discovered information became known to them to seek to amend the complaint. The *Pugh* matter did not even pertain to a scenario of newly discovered evidence. Instead, at issue in *Pugh* was a legal deficiency and "the defendants pointed out this deficiency before the plaintiffs filed their second amended complaint, but they chose not to remedy it." 521 F.3d at 698. On that basis, not because plaintiff may have had newly discovered evidence for one month, the Court in *Pugh* would not allow a third amendment to the complaint. *Id.*

III. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their request for reconsideration and allow Plaintiffs to amend the AC and file the PSAC.

DATED: July 22, 2008

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CERTIFICATE OF SERVICE

I, Samuel H. Rudman, hereby certify that on July 22, 2008, I caused a true and correct copy of the attached:

> Reply Memorandum of Law in Further Support of Plaintiffs' Motion for Reconsideration

to be served: (i) electronically on all counsel registered for electronic service for this case; and (ii) by first-class mail to any additional counsel.

/s/ Samuel H. Rudman
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